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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,485	05/06/2005	El Hassane Larhrib	N1518-WPT-EAS	2351
23456 7590 03/27/2009 WADDEY & PATTERSON, P.C. 1600 DIVISION STREET, SUITE 500 NASHVILLE, TN 37203			EXAMINER HAGHIGHATIAN, MINA	
			ART UNIT	PAPER NUMBER
			1616	
			NOTIFICATION DATE	DELIVERY MODE
			03/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@IPLAWGROUP.COM
BFL@iplawgroup.com

Office Action Summary	Application No. 10/501,485	Applicant(s) LARHRIB ET AL.	
	Examiner MINA HAGHIGHATIAN	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Haghighatian.

Receipt is acknowledged of the Amendments and Remarks filed on 12/24/08.

Claims 1, 2 and 4-25 have been amended and claim 3 has been cancelled. No new claims have been added. Accordingly, claims **1-2 and 4-25** remain pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 provides for the use of hollow microporous particles, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 24 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2 and 4-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gombotz et al. (hereafter Gombotz) (WO 90/13780).

Applicant claims a method of producing hollow microporous particles comprising a composition containing one active principle and at least one expansion agent, followed by cooling the composition and wherein all or part of said at least one expansion agent is removed.

Determination of the scope and content of the prior art

(MPEP §2141.01)

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Gombotz et al disclose, on page 4, lines 4-26, a method of making a particle comprising dissolving a polymer/active agent into a solvent to form microparticles. The microparticles placed into a vessel containing a non-solvent and are cooled below the freezing point of the solution. Upon the thawing of the solution the solvent is slowly extracted into a non-solvent, resulting hardening microspheres. Page 9, table 1, teaches that the solvent can be acetone or methanol. Examples, such as Example 1 teach that to the formulation, 300 ml of liquid nitrogen was added. The nozzle atomized the mixture into droplets which froze upon contacting the liquid nitrogen and formed microspheres which then sank onto the frozen ethanol. The container was removed from the freezer and the microspheres were filtered from the solvent. They were dried in a **vacuum** desiccator for 24 hours.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

Gombotz et al do not teach the expansion coefficient of the expansion agent.

Finding of prima facie obviousness

Rational and Motivation (MPEP §2142-2143)

It is the position of the examiner that since the prior art reference of Gombotz et al teach a method of producing hollow porous particles with an expansion agent as claimed by applicant, the expansion coefficient would have been obvious.

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It would have been obvious to one of ordinary skill in the art to have modified the teachings of Gombotz et al by including an expansion coefficient of the expansion agent used, however it is considered that expansion coefficients of agents are known and that since Gombotz et al is employing the same agents (such as methanol, ethanol, acetone, nitrogen) in the formation of his porous particles, the expansion coefficients are inherently disclosed. It is noted that **In re Best** (195 USPQ 430, C.C.P.A. 1997) and **In re Fitzgerald** (205 USPQ 594, C.C.P.A. 1980) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe **inherently includes functions** that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Response to Arguments

Applicant's arguments filed 12/24/08 have been fully considered but they are not persuasive. Applicant states that amendments made to claim 24 overcome the rejection of this claim under 35 U.S. C. 12, indefiniteness. However, the claim remains rejected, because it does not comply with the 112 rules. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Claim 24 does not recite how this USE is actually practiced. The claim should be amended to recite e.g. a method of producing a medicine comprising hollow particles... .

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Applicant argues that “In Gombotz, the hollow micro porous structure is obtained after freeze-drying. It is the freeze-drying step which forms the “porous structure”- which is only said to be produced in Example 1 (page 11, lines 21-24). In contrast, the very low temperature obtained by freezing in the process of the present application weakens the resistance of the structure of the active principal rendering it more brittle”. This is not persuasive because Gombotz teach that drying is done by vacuum and not freeze drying. The microparticles are formed at the time of atomizing the mixture into droplets which froze upon contacting the liquid nitrogen, however the drying happens later by vacuum. (Note: lines 21-24 of page 11, do not recite freeze drying).

Applicant argues that according to the invention, “...formation *in situ* of a porous structure without the requirement of a freeze-drying step” occurs. This is not persuasive. applicant argues limitations that are not recited in the claims. Freeze drying is not excluded form the instant claims.

Applicant argues “removal of the expansion agent occurs during pore formation”. This is not persuasive because again Applicant is arguing limitations that are not in the claims. Claims require formation of the hollow micro-particles and then it recites the step of removal of at least one expansion agent (see independent claims 1 and 24).

Applicant argues “the expansion agents used in the present invention have the ability to expand and have high vapor pressure characteristics”. This is not a persuasive argument against the prior art because Gombotz et al teach the same agents used in the instant claims such as acetone and menthol (specification also recites agents such as ethanol).

Applicant argues that Gombotz et al uses water as the “expansion coefficient”. This is not persuasive because as stated above Gombotz et al teaches using agents such as acetone or ethanol, just like the instant claims. Example 1 teaches using methylene chloride, ethanol, nitrogen and protein. There is no disclosure of water.

Applicant argues that Gombotz et al teach microparticles that at best contain 50% of active agents, whereas the instant particles can contain up to 100%. This is not commensurate with the scope of claims because none of the instant claims recite any amount of active agents in the particles.

All claims remain rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINA HAGHIGHATIAN whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghighatian/

Mina Haghighatian
Primary Examiner
Art Unit 1616